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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/888,114 | 06/22/2001 | Seung-Ho Choi | 19916-003001 | 9054 |
| 26161 | 7590 | 02/22/2006 | EXAMINER | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | | LUCAS, ZACHARIAH |
| ART UNIT | | PAPER NUMBER | | |
| 1648 | | | | |

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/888,114 | CHOI ET AL. | |
| | Examiner | Art Unit | |
| | Zachariah Lucas | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 December 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,3,5-22 and 42 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 and 13 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2,3,5,12,14-22 and 42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/12/05, 3/24/03.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

1. Claims 2, 3, and 5-22 are pending in the application. In the prior action, mailed on March 14, 2003, claims 2, 3, and 5-22 were pending, with claims 2, 3, 5, 12, and 14-22 were under consideration and rejected; and claims 6-11, and 13 withdrawn as to non-elected inventions.
2. In the Response of December 8, 2005, Applicant added new claim 42.
3. Claims 2, 3, 5, 12, 14-22, and 42 are currently under consideration.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on March 24, 2003, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.
5. The following references are in a foreign language accompanied by an English abstract. Due to this, the references have been examined only to the extent of the disclosure in the abstract.

JP 60-67413; and
WO 99/31106.

6. The information disclosure statement (IDS) submitted on December 12, 2005, is also in compliance with the provisions of 37 CFR 1.97. However, the sole reference cited therein was previously made of record and considered in the IDS of March 25, 2002. The reference has therefore been crossed off from the signed IDS.

Priority

7. Applicant's claim for priority to applications 09/829,405, 09/598,089, and PCT/US01/19625 per the decision of the Office of Petitions mailed on December 27, 2005 is acknowledged.

Specification

8. **(New Objection)** The disclosure is objected to because of the following informalities: the specification refers to the cephalosporin "cefozoprane" in several instances. See e.g., pages 11 and 19. The Applicant appears to be referring to the drug known in the art as - - cefozopran- -. See e.g., U.S. 5,994,340, column 3; and 5,968,253, column 4.

Appropriate correction is required.

Claim Objections

9. **(New Objection)** Claim 5 is objected to because of the following informalities: the claim refers to "cefozoprane." However, it appears that the cephalosporin that the claim was intended to refer to is known as - - cefozopran- -. Appropriate correction is required.

Double Patenting

10. **(Prior Rejection- Maintained)** Claims 2, 3, 5, 12, and 14-21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-11, 14-21, 24, 31, and 32-34 of U.S. Patent No. 6,248,360. It is noted that claim 22 was erroneously omitted from the prior rejection. However, the inclusion of this claim does not

affect the basis of the rejection. The rejection is also extended to new claim 42 on the basis of claim 11 of the patent.

The rejected claims read on a pharmaceutical composition comprising a biopolymer, a cephalosporin, a metal cation, and an absorption enhancer. The Applicant traversed the rejection in the paper submitted on September 17, 2003 by asserting that the Examiner has improperly applied teachings found in the specification of the patent, and not specifically found in the claims. The Applicant asserts that the specification of the patent may only be used to determine the meaning of terms in the claims. However, this assertion is not supported by the law.

The Applicant appears to be interpreting the cited language from the General Foods Corp. v Studeinggesellshaft Kohle mbH decision (23 U.S.P.Q. 2d 1839, 1446 (Fed Cir 1992)) as meaning that the disclosure of a prior patent is not prior art, and therefore may not be applied against claims in a later application by the same inventor. However, this is not an accurate interpretation. A review of the section of the General Foods decision cited by the Applicant illustrates the idea that there is a distinction between what has been claimed in a prior patent, and that which is prior art to the claims under consideration. Further, the decision also notes that while the disclosure may not be applied as prior art, the claims of the patent may, and that which falls within the scope of the claims, may be used to reject later claims for double patenting where the claims of the patent read on the same subject matter as that in the application under consideration. See e.g., General Foods, at page 1446 (quoting the decision of In re Sutherland, 146 U.S.P.Q. 485 (CCPA 1965) as follows: "the words of such claims cannot be treated as 'prior art,' ... but are looked to solely for the purpose of determining *what has already been patented*. They are not treated as prior art for the simple reason they are no more 'prior art' under the statute

than the specification.”). Thus, the quoted language of the General Foods decision is peripheral to, rather than contradictory to, the previously cited Vogel decision.

As indicated in the prior action, the MPEP clearly states that “those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent,” and that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.” See, MPEP 804 (quoting *In re Vogel*, 164 USPQ 619, 622 (CCPA 1970)). Rather, However, the fact that previously claimed subject matter, subject matter which can be identified by reference to portions of the specification supporting patented claims (see, Vogel) is not prior art does not prevent its application in a double patenting rejection against claims in a later application for subject matter that has already been claimed in a prior patent by the same inventor. As such, and because the language of the General Foods decision fails to contradict this policy, the Applicant’s arguments are not found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. **(Prior Rejection- Withdrawn)** Claims 2, 3, 5, 12, 14-16, 19, and 20 were rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al., U.S. Patent No. 6,248,360. In view of the grant of the Petition for Unintentionally Delayed claim to priority to this patent, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **(Prior Rejections- Withdrawn)** Claims 2, 3, 5, 12, and 14-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al., U.S. Patent No. 6,248,360. Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Choi in view of Watts et al., U.S. Patent 6,465,626. In view of the grant of the Petition for Unintentionally Delayed claim to priority to the Choi patent, the rejection is withdrawn.

15. **(Prior Rejection- Maintained)** Claims 2, 3, 5, 12, 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al., U.S. Patent 6,458,287, in view of Watts. The rejection is restated such that the claims are rejected over Scott in view of Watts et al., WO 98/30207. It is noted that, although claims 20 and 21 were inadvertently left out of the statement of the rejection in the prior action, the limitations of these claims were expressly discussed in the

rejection on pages 9 and 10 of the prior action. Thus, inclusion of the claims in the current statement of the rejection is not considered to change the ground of rejection. The Applicant traverses the rejection on the grounds that the Scott reference relates the use of many different types of macromolecules to be delivered, different types of complexing agents (including the metal cations). The Applicant asserts that there is nothing in the reference to guide those in the art towards the selection of the cephalosporins, the use of the cationic metals over the other listed complexing agents.

These arguments are not found persuasive. The reference specifically teaches the use of a microparticle comprising biopolymers and a metal cation, and indicates that such particles are useful for the delivery of any therapeutic agents, including antibiotics. See e.g., columns 19 and 20. Thus, it would have been obvious to those of ordinary skill to use such microparticles for any of the suggested therapeutic agents, including the suggested antibiotics.

Applicant's reference to the MPEP is noted. However, in the present case, the reference specifically teaches the microparticles used, and unlike the cases referenced by the MPEP, specifically identifies cephalosporins as being a useful compound in the disclosed formulations. It is noted that the decision of *In re Baird* , which found against the finding of obviousness, noted that the teachings of the reference in that case did not specifically disclose the claimed species, and in fact indicated a preference leading away from the claimed embodiment. 29 U.S.P.Q.2d 1550, at 1552 (CAFC 1994). In the present case, while the reference indicates that "in certain embodiments" protein or peptide agents are preferred, the reference provides no teachings to teach away from the use of the disclosed antibiotics, including cephalosporins. See e.g., columns 21-22. Thus, while the teachings of Scott may indicate that the particles disclosed therein have

broad applicability, the teachings nevertheless render the claimed particles obvious when read in combination with Watts as previously described. For these reasons, and the reasons of record, the rejection is maintained.

16. **(Prior Rejection- Withdrawn)** Claims 2, 3, 14, 15, and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al., U.S. Patent 4,616,008, in view of Platé et al, U.S. Patent 6,004,583 (of record in the IDS filed on March 25, 2002), and further in view of Watts. The rejection is restated such that the claims are rejected over Hirai in view of Platé and further in view of Watts et al., WO 98/30207. The Applicants arguments with respect to the combination of Hirai and Platé are found persuasive. The rejection is therefore withdrawn.

17. **(New Rejection- Necessitated by Amendment)** Claims 2, 3, 5, 12, 14-22, and 42 rejected under 35 U.S.C. 103(a) as being unpatentable over Scott in view of Watts as applied to claims 2, 3, 5, 12, 14-22 above, and further in view of Horwitz et al. (U.S. 5,783,561). Newly added claim 42 limits the claimed invention to embodiments wherein the cephalosporin is a third general cephalosporin. Neither Scott nor Watts specifically refers to the use of third general cephalosporins. However, as previously described, the Scott reference does teach the use of cephalosporins in general. In addition, the teachings of Horwitz indicate that the third generation cephalosporins were known in the art, and that they were preferable to other cephalosporins in certain respects. See e.g., column 4, lines 35-62. Thus, it would have been obvious to those in the art to have used any cephalosporin in the compositions suggested by Scott and Watts, and based

on the additional teachings of Horwitz, the third generation drugs would have been obvious as routine optimization of the composition for anti-bacterial use.

Because the Scott reference indicates that the compositions disclosed therein may be used with any number of biologically active compounds, including cephalosporins, those of ordinary skill in the art would have had a reasonable expectation of success in the use of third generation cephalosporins as the active agent. Thus, the combined teachings of these references render the claimed compositions obvious.

Conclusion

18. No claims are allowed.
19. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

U.S. 2005/0095294. This reference teaches in paragraph [0130] that Capmuls are non-ionic surfactants. See also, U.S. 2004/0048931, paragraph [0066].

U.S. Patents 6,458,772, 5,994,340, and 5,968,253. These references teach several of the cephalosporins, including several of the third generation cephalosporins, that were known in the art, and are identified in claim 5. See e.g., 6,458,772- columns 35 (esp. lines 19-27), and 60-62; 5,994,340- column 3; 5,968,253- column 4 (esp. lines 55-66).

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

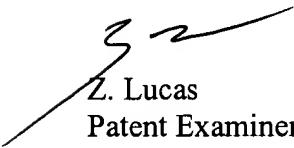
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES C. HOUSEL 2/20/06
SUPERVISORY PATENT EXAMINER
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